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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,332	11/21/2000	Narmada Shenoy	038602-1060	9626

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EXAMINER	
JONES, DWAYNE C 10	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/716,332	SHENOY ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,10,11,13-34,36,38-48 and 50-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3-5,7,8,10,11,13-34,36,38-48 and 50-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48 and 50-87.

2. Claims 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48 and 50-87.

3. Claims 2, 6, 9, 12, 35, 37 and 49 were cancelled as per the amendment of December 6, 2002.

Response to Arguments

4. Applicant's arguments filed on December 6, 2002 have been fully considered but they are not persuasive with respect to the rejection under 5 U.S.C. 103(a) as being unpatentable over Tang et al. Specifically, applicants allege that Tang et al. do not render the instant invention obvious due because, inter alia, there is no prima facie obviousness made especially in view of In re Baird.

5. Applicants argue that because a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. In addition, applicants appellant alleges that the elected compound requires the R^8 and R^{10} are methyl and that of R^9 is a propionic acid moiety. However, the prior art reference of Tang et al. teach of the substituted 2-indolinone compounds of formula (III), (see column 10). In fact, Tang et al. specifically teach of "a preferred embodiment of the invention, the compound of formula III is 3-[(2,4-Dimethylpyrrol-5-yl)methylene]-2-indolinone, (see column 11, lines 6-9). Moreover, Tang et al. also provide the skilled artisan with the motivation to optionally substitute the pyrrole-2-indolinone compounds

with alkyl groups as well as carboxylic acid and alkyl-carboxylic acid moieties. Clearly, since one having ordinary skill in the art is provided with the explicit motivation to utilize the "preferred embodiment" of a substituted pyrrole moiety of this 2-indolinone compound, it would have been obvious and well within the purview of the skilled artisan to include other substituent groups, namely alkyl-carboxylic acid moieties, especially when Tang et al. recite this small list of substituents, (see column 10, lines 63, 64, 66 and 67). Fore these reasons and the reasons cited in the previous Office action the prior art reference of Tang et al. render the elected species of March 28, 2002 as well as the instantly claimed compound of Formula (I) obvious.

Claim Objections

6. Claim 78 is objected to because of the following informalities: the claim has periods after the subletters of " a." and "b.". It is recommended that these periods be replaced with a parenthesis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The rejection of claims 78 and 80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a protein kinase related disorder, does not reasonably provide enablement for preventing a protein kinase related disorder is withdrawn in response to the amendment of December 6, 2002.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3-5, 7, 8, 10, 11, 13-34, 36, 38-48 and 50-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The indolinone compound of Formula (I) is missing variable R^6 from the structure. In addition, the variable of R^{10} is not defined or described in each of these claims. Accordingly, these claims are deemed vague and indefinite.

Claim Rejections - 35 USC § 102

10. The rejection of claim 1 under 35 U.S.C. 102(b) as being clearly anticipated by Tang et al. U.S. Patent No. 5,792,783 is withdrawn in response to the amendment of December 6, 2002.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. The rejection of claims 1-84 under 35 U.S.C. 103(a) as being unpatentable over Tang et al. U.S. Patent No. 5,792,783 is maintained and repeated. Tang et al. teach of compounds, in particular those of formula (III), which modulate, regulate and/or inhibit tyrosine kinases and its signal transduction, (as cited from column 1, lines 9-17 and from column 10, line 31 to column 11, line 8). For these reasons, the compounds of Tang et al. are effective in treating various disorders related to unregulated tyrosine kinase signal transduction, which includes cell proliferative disorders, such as cancers, blood vessel proliferative disorders, arthritis, fibrotic disorders, (see column 8, lines 41-63 and columns 13 and 14). In fact, Tang et al. specifically teach of "a preferred embodiment of the invention, the compound of formula III is 3-[(2,4-Dimethylpyrrol-5-yl)methylene]-2-indolinone, (see column 11, lines 6-9). Moreover, Tang et al. also provide the skilled artisan with the motivation to optionally substitute the pyrrole-2-indolinone compounds with alkyl groups as well as carboxylic acid and alkyl-carboxylic acid moieties. Clearly, since one having ordinary skill in the art is provided with the explicit motivation to utilize the "preferred embodiment" of a substituted pyrrole moiety of this 2-indolinone compound, it would have been obvious and well within the purview of the skilled artisan to include other substituent groups, namely alkyl-carboxylic acid moieties, especially when Tang et al. recite this small list of substituents, (see column 10, lines 63, 64, 66 and 67).The claims differ from the reference by reciting a more limited genus than the reference. However, it would have been obvious to one having

ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merk & Co. vs. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Conclusion

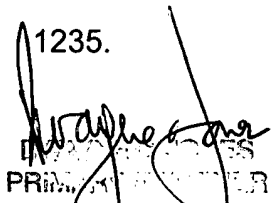
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Tech. Ctr. 1614
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